OCT - 6 2000

K002332

4 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR § 807.92.

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Director of R & D

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2568 Bristol Circle
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Common Names: EEG SPIKE AND EVENT DETECTOR Module

Classification Names: Electroencephalograph
Analyzer, spectrum, Electroencephalogram signal

Predicate Devices: The XLTEK EEG SPIKE AND EVENT DETECTOR Module is substantially equivalent in terms of safety and effectiveness to the Persyst Spike Detector by Persyst Consulting Services, Inc. [FDA 510(k) #K950117] and the Harmonie SENSA Module by Stellate Systems Inc. [FDA 510(k) #K960273].

Description: The XLTEK EEG SPIKE AND EVENT DETECTOR Module is software that is intended to be used by an EEG acquisition, display and storage device for long term monitoring and to aid in the identification of spikes and events from digital electroencephalographic signals by qualified medical practitioners.

The module performs automatic detection of waveforms and has a user interface to configure

spike detection, event detection and newborn event detection parameters.

The user interface is designed to be simple, intuitive and able to understand the medical terms of technologists and doctors.

Substantial Equivalence:

The XLTEK EEG SPIKE AND EVENT DETECTOR Module is substantially equivalent in terms of safety and effectiveness to the Persyst Spike Detector by Persyst Consulting Services, Inc. [FDA 510(k) #K950117 and the Harmonie SENSA Module by Stellate Systems Inc. [FDA 510(k) #K960273].

Indications for Use:

The XLTEK EEG SPIKE AND EVENT DETECTOR Module is intended to be used by an EEG acquisition, display and storage device (e.g. XLTEK NeuroWorks FDA 510(k) #K980214) for long term monitoring and to aid in the identification of spikes and events from digital electroencephalographic signals by qualified medical practitioners.

The detection feature considerably reduces the time that technologists would require to review long term (24 + hours) studies. The Module highlights regions and times of interest in the EEG, so that technologists can save time in performing analysis of EEG data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Ms. Debbie Davy
Research and Development Administration
Excel Tech, Ltd.
2568 Bristol Circle
Oakville, Ontario
Canada L6H 5S1

Re: K002332
Trade Name: EEG Spike and Event Detector Module
Regulatory Class: II
Product Code: GWQ
Dated: July 31, 2000
Received: August 1, 2000

Dear Ms. Davy:

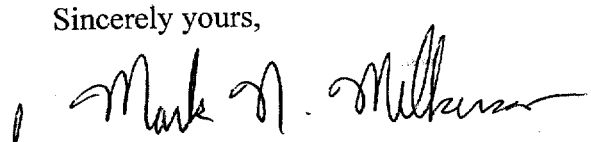
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K002332

Device Name: EEG SPIKE AND EVENT DETECTOR Module

Indications for Use: The XLTEK EEG SPIKE AND EVENT DETECTOR Module is intended to be used by an EEG acquisition, display and storage device (e.g. XLTEK NeuroWorks FDA 510(k) #K980214) for long term monitoring and to aid in the identification of spikes and events from digital electroencephalographic signals by qualified medical practitioners.

(PLEASE DO NOT WRITE BELOW THIS ~~LINE~~ – CONTINUE ON ~~ANOTHER PAGE~~ IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002332

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21§ CFR 801.109)

(Optional Format 1-2-96)